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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,125	ANTONSSON ET AL.	
	Examiner	Art Unit	
	A R Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/048,016.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Letter*.

RD

DETAILED ACTION

Claims 1-5 are pending.

Submitted Information Disclosure Statement (I.D.S) is noted.

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. The claims are directed to various "modified" polypeptides, in order to conduct a reasonable search to determine whether or not the polypeptide has been taught or similar structure was previously disclosed, sequence listing should be provided. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Claim Rejections - 35 USC ∋ 112

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for recitation of "intentionally modified" this is a relative term, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. In the instant case, the said definition has many meanings, what Applicants' regard as "modified" others might not and vise versa, and the specification does not provide clear teaching as to what is and is not considered to be Amodified protein. Moreover, claim 1 is vague and indefinite for recitation of "type-specific epitope(s)" the intended metes and bounds of the epitopes are not defined. The claim has been interpreted in light of the specification and since the specification is extremely deficient in providing adequate teaching it is not clear what the said limitation intends to cover. This affects the dependent claims.

The term "derived" in claim 2 is a relative term, which renders the claim indefinite. The term "derived" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Is this a full-length L1 protein or a partial protein? This affects claim 3.

Claim 3 is vague and indefinite, the metes and bounds of the intended L1 is not defined. A specific sequence identification number should identify the claimed polypeptide; so one can be apprised of its actual size and secondly an adequate search can be conducted.

Claim 4 is vague and indefinite; is the fused L1 protein different or the same as the original L1? The claim has been interpreted in light of the specification and since the

specification is extremely deficient in providing adequate teaching it is not clear what the said limitation intends to cover.

Claim 5 is indefinite for recitation of "comprising" to have comprising there has to more than one element present, presently VLP is the only one element defined.

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim Rejections - 35 USC ∋ 112

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specifically substituted amino acids of HPV-16 L1 capable of forming a VLP while the HPV 16 L1 has lost certain epitopes, does not reasonably provide enablement for modified L1 for any and all HPVs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification is extremely deficient in providing adequate teaching for the claimed invention. Applicants are reminded that this field is considered to be highly unpredictable, as applicants own statement throughout the disclosure is testament to the unpredictability of the field, and absent adequate teaching one of ordinary skill in the art would be required to conduct large quantity of undue experimentation to enable the claimed invention. The sequences of various papillomaviruses are different from one another, and there are no common structures that exist between all L1 proteins. Hence, substituting one set of amino acids in a well known L1 protein does not translate into modification of all HPV L1 capsid protein. It even appears applicants are directing the invention or alluding to the fact that

their invention is a gene therapy, but no construct has been taught, no expression of any gene, even a marker gene, has been disclosed. Where is a teaching for introduction of any gene or any antigen or any epitope into cells? No data has been shared with the Office, so no independent opinion can be rendered. The VLP could be subject to multiple proteases that are present at cellular milieu and dissolve the protein, while no peptide would get a chance of being expressed. The disclosure provides no examples for broad scope of claimed invention, Applicants are expecting others to enable their invention while they are obtaining patent protection, but this cannot be, especially in an unpredictable field. Absent teaching by the applicant one ordinary skilled in the art would be required to conduct large quantity of undue experimentations to enable the claims, see In re Vaeck, 20 USPQ2d 1438 (CA FC 1991, at page 1445) wherein the board has indicated that Athere must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentations. Applicants cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988)*.

Claim Rejections - 35 USC ∋ 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. In the instant disclosure, the applicants have "modified" HPV-16 L1 protein only, and have identified only a few regions within the HPV-16 L1 region which qualify as antibody neutralizing regions. The specification, however, does not set forth the metes and bounds of all modified peptides, or fusion peptides of all other modified L1 proteins that are encompassed within the claimed invention. Moreover there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed regions or where the region may encompass for all other HPV capsid proteins . See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to

make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA=s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Ψ. Accordingly, the specification does not provide a written description of the invention Ψ.

and at pg 1406:

> a generic statement such as Avertebrate insulin cDNA≅ or Amammalian insulin cDNA,≅ without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and Ψ conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Ψ. Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC ∋ 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloch et al (WO 97/46693).

The claims and teaching of the above cited reference anticipates the claimed invention. The above cited reference taught a non-infectious virus-like particle (VLP) wherein the a region of the L1 is substituted for a second protein (see the abstract, and the claims). The genus taught in the above cited reference also incorporates the specific species now recited in claim 3. The above cited art is pioneering invention and is entitled to broad interpretation, especially in view of lack of specific sequence identification of a construct by the present Applicants.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Gissmann et al (WO 96/11272).

The claims and teaching of the above cited reference anticipates the claimed invention. The above cited reference taught a structural protein of L1 wherein several sections have been deleted and still form virus like particles (VLPs) and which further were fused to a second peptide such as L2 (see the abstract, and the claims). The deleted L1 meets the Amodified≅

limitation and the fusion of L2 to L1 meets the "fusion peptide.≅ Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Claim Rejections - 35 USC ∋ 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1- 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Burger et al (WO 99/48518).

The claims and teaching of the above cited reference anticipates the claimed invention. The above reference taught a composition comprising a fusion protein that does not contain any papillomavirus non-specific epitopes and auxiliary agents and at least fusion protein is L1 and E protein of papilloma virus (see the abstract). The deleted L1 meets the Amodified≅ limitation and the fusion of E protein fusion to L1. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Gissmann et al (U.S. Patent No. 6,066,324).

The claimed invention is anticipated by the product disclosed in any one of claims 1-8 of above cited patent. The above cited patent taught a modified L1 protein. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC ∋ 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Bloch et al (U.S. Patent No. 6,420,160 B1).

The claims and teaching of the above cited reference anticipates the claimed invention. The above cited reference taught a non-infectious virus-like particle (VLP) wherein the a region of the L1 is substituted for a second protein (see the abstract, and the claims). The non-infections L1 meets the Amodified≅ limitation and the chimeric of L1 to E7 of claim 2 of the cited patent meets the Asecond peptide≅ limitations. In addition, they taught fusion of L1 and L2, see Column 1, lines 50-53. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Gissmann et al (U.S. Patent No. 6,361,778 B1).

The claimed invention is anticipated by the product disclosed in any one of claims 1-5 of above cited patent. The above cited patent taught a modified L1 protein. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Gissmann et al (U.S. Patent No. 6,066,324).

The claimed invention is anticipated by the product disclosed in any one of claims 1-8 of above cited patent. The above cited patent taught a modified L1 protein. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Please note the priority given to the present application is as of filing date of 01/20/2004. None of the limitations that are present in claim 3 were taught or present in previous prior applications. Applicants can point the Office to specific page for support.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al (J. of Virology, June 1999, pages 4882-4889), and McCarthy et al (WO 99/13056).

White et al taught characterization of major neutralizing epitopes of human papillomavirus (see the abstract). This differs since they not teach VLP's method in gene therapy.

McCarthy et al (WO 99/13056) taught a method of formulating homogeneous virus like particles (VLPs) of all papillomavirus types wherein the VLPs containing moieties wherein that

moiety could be a DNA, or peptide (see for example claim 21 and top of page 14). They also taught various Ainstructions≅ of making their VLPs (see for instance Tables 1 and 2). This only differs to the extent of exact that they did not modify the L1 protein.

However, it would have been obvious to one of ordinary skill in the art at the time of filing to take the teaching of McCarthy et al and modify the VLPs by removing its epitopes as taught by White et al to decrease antibody response to the L1 and wherein the VLP can be utilized in gene therapy wherein heterologous moieties inside the VLPS can be utilized in treating diseases. One of ordinary skill in the art at the time of filing being familiar with the above cited art would not have anticipated any unexpected results. Hence, the claimed invention as a whole is ***prima facie*** obvious absence unexpected results.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over, Christensen et al (J. of General Virology, 1994, Vol. 75, pages 2271-2276), and Touze et al (Nucleic Acid Research, 1998, Vol. 26, No. 5, pages 1317-1323).

Christensen et al taught the presence of neutralizing epitopes human papillomavirus capsid protein (see the abstract). This differs since they not teach VLP's method in gene therapy.

Touze et al taught papillomavirus like particles can be used to deliver foreign DNA in general and in particular they taught HPV-16 L1 can be sued to deliver foreign material to cells (see the abstract). In addition, they taught the advantages of VLP for gene transfer over other viruses (see page 1322, right column, last paragraph). This only differs to the extent of exact that they did not modify the L1 protein.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to take the teaching of Touze et al and modify the VLPs by removing its epitopes as taught by Christensen et al, which discussed the highly conformational nature of the most neutralizing epitopes. The skilled artisan would have been motivated to modify the epitopes to decrease antibody response to the L1 and wherein the VLP can be utilized in gene therapy wherein heterologous moieties inside the VLPS can be utilized in treating diseases. Hence, the utility of VLP is taught and the removals of epitopes are also taught in the prior art. Thus, one of ordinary skill in the art at the time of filing being familiar with the above cited art would not have anticipated any unexpected results. Hence, the claimed invention as a whole is ***prima facie*** obvious absence unexpected results.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over, Christensen et al (J. of General Virology, 1994, Vol. 75, pages 2271-2276), and McCarthy et al (WO 99/13056).

Christensen et al taught the presence of neutralizing epitopes human papillomavirus capsid protein (see the abstract). This differs since they not teach VLP's method in gene therapy.

McCarthy et al (WO 99/13056) taught a method of formulating homogeneous virus like particles (VLPs) of all papillomavirus types wherein the VLPs containing moieties wherein that moiety could be a DNA, or peptide (see for example claim 21 and top of page 14). They also taught various instructions of making their VLPs (see for instance Tables 1 and 2). This only differs to the extent of exact that they did not modify the L1 protein.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to take the teaching of McCarthy et al and modify the VLPs by removing its epitopes as taught by Christensen et al, which discussed the highly conformational nature of the most neutralizing epitopes. The skilled artisan would have been motivated to modify the epitopes to decrease antibody response to the L1 and wherein the VLP can be utilized in gene therapy wherein heterologous moieties inside the VLPS can be utilized in treating diseases. Hence, the utility of VLP is taught and the removals of epitopes are also taught in the prior art. Thus, one of ordinary skill in the art at the time of filing being familiar with the above cited art would not have anticipated any unexpected results. Hence, the claimed invention as a whole is ***prima facie*** obvious absence unexpected results.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over, Carter et al (J. of Virology, Nov. 2003, Vol. 77, No. 21, pages 11625-11632), and Touze et al (Nucleic Acid Research, 1998, Vol. 26, No. 5, pages 1317-1323).

Carter et al characterized the L1 protein regions that play significant role in antibodies binding (see Table 1, and the abstract). This differs since they not teach VLP's method in gene therapy.

Touze et al taught papillomavirus like particles can be used to deliver foreign DNA in general and in particular they taught HPV-16 L1 can be sued to deliver foreign material to cells (see the abstract). In addition, they taught the advantages of VLP for gene transfer over other viruses (see page 1322, right column, last paragraph). This only differs to the extent of exact that they did not modify the L1 protein.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to take the teaching of Touze et al and modify the VLPs by removing its epitopes as taught by Carter et al, which discussed the highly conformational nature of the most neutralizing epitopes. The skilled artisan would have been motivated to modify the epitopes to decrease antibody response to the L1 and wherein the VLP can be utilized in gene therapy wherein heterologous moieties inside the VLPS can be utilized in treating diseases. Hence, the utility of VLP is taught and the removals of epitopes are also taught in the prior art. Thus, one of ordinary skill in the art at the time of filing being familiar with the above cited art would not have anticipated any unexpected results. Hence, the claimed invention as a whole is ***prima facie*** obvious absence unexpected results.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi
5/16/2005

ALI R. SALIMI
PRIMARY EXAMINER

Application No.: 10/759,125

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s)

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: See Page 2 of the Office Action

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE